Frequently Asked Questions

VHA Directive 1058.03, Federalwide Assurance (FWA), Institutional Review Board (IRB) Registration and Memoranda of Understanding (MOU) for IRB Reliance

FWA and FWA Addendum

Q: The superseded VHA Handbook 1058.03 (November 21, 2014), "Assurance of Protection for Human Subjects in Research," required that Department of Veterans Affairs (VA) medical facilities engaged in research involving human subjects or human biological specimens must hold an effective FWA approved by the Department of Health and Human Services Office for Human Research Protections (HHS-OHRP) with an effective VA FWA Addendum approved by the Office of Research Oversight (ORO). Is this still the case?

A: Not entirely. An FWA is only required for facilities conducting non-exempt human subjects research. If a facility is only conducting research involving de-identified data or biospecimens, or only conducting exempt human subjects research, that facility does not require an FWA. However, for all VA facilities conducting any kind of research, the Office of Research and Development (ORD) requires a research infrastructure with a Research and Development (R&D) Committee of record and Associate Chief of Staff for Research (ACOS/R) or Research Coordinator. Programmatic infrastructure requirements are described in VHA Directive 1200.02 "Research Business Operations" and VHA Directive 1200.01 "Research and Development Committee." VHA Directive 1200.05 §5.f(9) states: "Each VA medical facility Director is responsible for … Requesting [Chief Research and Development Officer (CRADO)] approval when the VA facility wants to establish a new [Human Research Protection Program (HRPP)], change its IRB(s) of Record, or wants its internal IRB to serve as an IRB of Record for a non-VA entity. ***NOTE:*** *All IRBs overseeing VA human subjects research regardless of the type described above must meet all the IRB requirements described in 38 CFR Part 16.*"

Q: To whom in ORO do I submit the FWA and VA FWA Addendum?

A: The FWA and VA Addendum are submitted to the ORO FWA Staff at OROFWA@VA.GOV. Questions about the FWA and VA Addendum may be sent to that address also.

Q: Where are the VA instructions for updating/renewing the FWA and VA Addendum located?

A: Please visit www.VA.gov/ORO/FWA.asp for VA instructions for updating/renewing the FWA and VA Addendum.

Q: If I have trouble creating or entering information in the FWA should I contact HHS-OHRP directly?

A: No. ORO Staff members monitoring the mailbox at OROFWA@VA.GOV serve as your liaison with HHS-OHRP to reduce the number of contacts with and not overwhelm the HHS-OHRP staff. ORO staff can assist you with preparing and entering the FWA if you have trouble as ORO FWA staff are designated as system administrators on the HHS-OHRP system.

Q: Why do I need to complete the VA FWA Addendum?

A: The HHS-OHRP FWA is a generic form for all institutions that use it as their Assurance for federally conducted or supported research involving human subjects. The VA Addendum requires the VA facility to further assure that all of its activities related to human subjects research will comply with all requirements of VA regulations at Title 38 Code of Federal Regulations Part 16 (38 CFR 16), and all other applicable VA policies and procedures, including policies and procedures of ORO and ORD, issued in Handbooks and other relevant authorized Directives.

The VA Addendum stipulates that use of an IRB operated by another institution requires an MOU between the institutions. The VA facility Institutional Official certifies on this Addendum that any MOU executed for the purpose of using an IRB operated by another institution will contain a commitment from that institution to provide complete access to all IRB records and related documents pertaining to the review, approval, and oversight of VA research studies to the VA medical facility and ORO upon request. This commitment applies to VA-affiliated medical and dental schools or any other IRBs approved for use by VA.

Q: For personnel signing the FWA, is specific formal training still required by ORO?

A: No. The medical facility Director is responsible for being familiar with the requirements in the Federal Policy for the Protection of Human Subjects (Common Rule) and the ethical principles governing human subjects research in the Belmont Report. *See* VHA Directive 1058.03 §5.f(2). When medical facility Directors sign the VA Addendum they are indicating they are familiar with the requirements of the Common Rule. Familiarity may be gained through either formal training [*for example, see* https://www.research.va.gov/programs/orppe/education/ord_training/options.cfm] or other less formal means. The Belmont Report is accessible at https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report. A summary of the aforementioned requirements and principles is available on HHS-OHRP's website at https://www.hhs.gov/ohrp/education-and-outreach/human-research-protection-program-fundamentals/index.html/assurance-training.

Q. Who can serve as the Human Protections Administrator (HPA) for the FWA?

A. The HPA should be someone familiar with the daily operations of the research program, such as the ACOS/R or R&D Coordinator, the Administrative Officer, the R&D Committee Administrator or IRB Administrator. The Research Compliance Officer should not serve in this role.

Q. The FWA Item #2 asks for "Institutional Components" to be listed in that section. What does the VA facility list in that section?

A. The Instructions for the FWA indicate that institutions should list all components over which the Institution has legal authority that operate under a different name that will be covered by the FWA. The purpose of this section on the FWA is to help HHS-OHRP identify to which FWA-holding Institution a certain component belongs if HHS-OHRP receives a complaint about the component. In VA, examples of institutional components are outpatient clinics or other campuses operated by and part of the parent VA Facility that may have different names. An example is VA Maryland Health Care System which includes Perry Point VA Medical Center and other campuses. Only those components where VA non-exempt human subjects research would be conducted should be listed. If the VA facility has several names such as a Congressional memorial name and also VA Health Care Center XX or other names, they can be listed in this section. Outpatient clinics or programs used by the VA facility through a contract for services are not covered by the FWA and should not be listed on the FWA because they are separate legal entities.

Q: If our facility doesn't have an **internal IRB (operated by our facility)** and relies on several other external IRB(s), which committee should be documented on our FWA?

A: Only IRBs operated by the VA medical facility must be designated on the FWA or, in the absence of an IRB operated by the VA medical facility, only the external IRB that oversees the greatest percentage of the VA medical facility's non-exempt human subjects research studies must be designated on the VA medical facility's FWA. *See* VHA Directive 1058.03 §6.a(2).

Q: Our facility relies on the IRB of our academic affiliate as our <u>primary</u> IRB. The current VHA Directive 1058.03 (September 17, 2020) in § 3.i. implies that IRBs of Record may or may not be designated on the FWA. Does this IRB need to be designated on our FWA?

A: VHA Directive in § 3.i. defines "IRB of Record" as any IRB relied upon by a VA medical facility for review and oversight of the facility's human subjects research, regardless of whether it is designated on a VA medical facility's FWA. VHA Directive 1058.03 in § 6.a(2) states that FWAs for VA medical facilities must designate at least one IRB of Record as follows: (a) All IRBs operated by a VA medical facility (internal IRBs) must be designated on the VA medical facility's FWA; (b) If a VA medical facility does not operate its own internal IRB, the external IRB that oversees the greatest percentage of the VA medical facility's non-exempt human subjects research studies must be designated on the VA medical facility's FWA. If your facility does not have an internal VA IRB(s), this will likely be the university affiliate IRB or the VA medical facility IRB that you <u>primarily</u> rely upon. NOTE: When an IRB of Record is operated by an entity other than the VA medical facility, an MOU or other written agreement is required.

Q: What if our affiliate has multiple IRBs/panels that oversee the greatest percentage of our non-exempt human subjects research studies?

A: You should list on the FWA only IRBs operated by your medical facility or, in the absence of an IRB operated by the VA medical facility, only the external IRB (including all component boards/panels) that oversees the greatest percentage of the VA medical facility's non-exempt human subjects research studies. For example, if your affiliate operates IRB00001234 and IRB0001235 and your protocols may be reviewed by either IRB/panel, list both on the FWA.

Q: Who needs to sign an **FWA Addendum**?

A: Only the medical facility Director and the ORO Executive Director or designee need to sign the VA FWA Addendum. *See* VHA Directive 1058.03 §6.a(3).

Q: When must the FWA and VA Addendum be updated for changes in the individuals listed on the FWA?

A: If a new VA medical facility Director, Acting VA medical facility Director, or HPA is appointed, the FWA and the VA FWA Addendum must be revised to reflect the appointment and then submitted to ORO within 60 days of the appointment so as to ensure timely submission to HHS-OHRP (through ORO FWA staff) within 90 days of the change occurring. *See* VHA Directive 1058.03 §6.a(5). NOTE: If the Acting medical facility Director will be in that acting position for less than 60 days, the requirement to revise the FWA and VA FWA Addendum does not apply.

Q: Can an **Acting facility Director** sign the FWA and FWA addendum?

A: Yes. If the acting facility Director is acting or interim pending appointment of a new Director, the acting Director may sign the FWA and FWA addendum. An acting Director during short term absences of the permanent Director, such as for leave or travel, may not sign the FWA and VA Addendum on behalf of the Director.

Q: What **changes to the FWA** must be submitted to ORO?

A: The FWA and VA Addendum must be updated for changes in the legal name of the institution, the Signatory Official, the HPA, and administrative and programmatic changes such as a change in the designated IRB. Updates must be submitted within 60 days to ORO FWA staff at OROFWA@VA.GOV for review so as to ensure timely submission to HHS-OHRP through ORO FWA staff within 90 days of the change. *See* VHA Directive 1058.03 §§5.f(3) and 6.c.

Q: May we submit the VA FWA Addendum with an electronic signature?

A: Yes; ORO prefers electronic signature on the VA FWA Addendum, but will accept handwritten signatures. The acceptable electronic signature is through a PIV certificate.

Q: What if our facility changes its name; do we have to update our FWA?

A: HHS-OHRP requires that the FWA be updated for changes regarding the legal name of the institution, among other things. If your facility changes its legal name, or adds a Congressional memorial name, the FWA and VA FWA Addendum must be updated. ORO FWA staff at OROFWA@VA.GOV can assist with this change.

Q: The superseded VHA Handbook 1058.03 indicated that initial FWA approval period was typically for 5 years. What is the current policy requirement?

A: FWAs and VA FWA Addenda for VA medical facilities are typically approved for a period of five (5) years and are inactivated if renewals have not been approved by HHS-OHRP and ORO, respectively, prior to the end of the FWA's and VA FWA Addendum's approval period. *See* VHA Directive 1058.03 §6.e. Any FWA renewal or update that is submitted electronically, and approved by HHS-OHRP, begins a new 5-year effective period. The FWA expiration date is shown in Item #9 on the last page of the FWA approved by HHS-OHRP.

Q: Where can I go to check the status of my facility's FWA or to verify whether a proposed collaborating institution has an FWA that is current?

A: The HHS-OHRP Database is located at https://ohrp.cit.nih.gov/search/search.aspx?styp=bsc. You can search by name of the Institution, by IRB Organization Number (IORG0000XXX), IRB Number (IRB0000XXX) or FWA number (FWA000XXX).

You can search for FWAs and IRB registrations submitted for update in the last 60 days to see if they are still pending. If pending longer than 2-3 weeks at HHS-OHRP, contact the ORO FWA staff at OROFWA@VA.GOV

IRB Registration

Q: Which **IRBs have to be designated** on our facility's FWA?

A: The prior requirement that all IRBs used by a VA medical facility be designated on the VA medical facility's FWA has been changed such that only IRBs operated by the VA medical facility must be designated on the FWA or, in the absence of an IRB operated by the VA medical facility, only the external IRB that oversees the greatest percentage of the VA medical facility's non-exempt human subjects research studies must be designated on the FWA. *See* VHA Directive 1058.03 §7.b.

Q: Our facility has multiple IRBs that we rely upon listed on our FWA that are not required by VHA Directive 1058.03 to be designated; do we have to remove those IRBs from our FWA?

A: No. However, IRBs that your facility no longer relies upon should be removed from the FWA.

Q: Do we still have to report routine **IRB roster or** HHS-OHRP **IRB Registration changes** to ORO?

A: No. That requirement has been removed from the current VHA Directive 1058.03. However, initial registrations of IRBs operated by VA medical facilities must be submitted through ORO FWA staff to HHS-OHRP. The VA medical facility operating the IRB must provide the initial IRB membership roster to ORO FWA staff at OROFWA@VA.GOV for review (either the local roster or the proposed HHS-OHRP IRB registration). *See* VHA Directive 1058.03 §7.b(1). NOTE: ORO still advises facilities that have questions about roster changes to contact the ORO FWA Staff at OROFWA@VA.GOV. ORO compliance workgroups will still review the suitability of roster changes during site visits. *See* VHA Directive 1058.03 §7.c.

Q: The superseded VHA Handbook 1058.03 indicated that IRB registrations must be renewed every 3 years, or as otherwise required by HHS-OHRP. What is the current policy requirement?

A: IRB registrations must be renewed as required by HHS-OHRP. VA medical facilities must meet HHS-OHRP requirements for updating information required in the IRB Registration. *See* VHA Directive 1058.03 §7.b(2). Currently, HHS-OHRP requires that each IRB must renew its registration every 3 years. An IRB registration also must be updated within 90 days after changes occur regarding the contact person who provided the IRB registration information and/or the IRB chairperson. Any renewal or update that is submitted to, and accepted by, HHS-OHRP begins a new 3-year effective period.

MOUs/IRB Reliance Agreements

Q: What is an IRB MOU?

A: A Memorandum of Understanding (MOU) is a written agreement between two or more entities for reliance upon the other entity/ies' IRB(s). Such written agreements document the relationship and define the respective roles and responsibilities of each entity within that relationship. These written agreements may also be referred to as "IRB Signatory Agreements," "Reliance Agreements," or "IRB Authorization Agreements." *See* VHA Directive 1058.03 §3.j. When the facility engages the services of another entity's IRB as its IRB of Record, the Institutional Official (IO; i.e., the medical facility Director) is responsible for: (a) establishing and signing an MOU (or other type of written IRB agreement) to document pertinent roles and responsibilities relative to the use of that other entity's IRB as an IRB of Record for the VA medical facility; (b) ensuring revision or amendment of the MOU as conditions outlined in the MOU change, including changes of IO, and submitting such revisions to ORO within 30 days of execution; (c) ensuring the submission to ORO of a signed copy of the MOU for any IRBs designated as IRBs of Record on a VA medical facility's FWA within 30 days of execution; and (d) ensuring MOUs required under VHA Directive 1058.03 are kept on file at the VA medical facility and made available to ORO and other oversight and accrediting bodies upon request and to the extent allowed by applicable law, regulation, and policy. *See* VHA Directive 1058.03 §5.f(10). *See also* MOU Checklist: http://www.va.gov/ORO/orochecklists.asp.

Q: What is the policy regarding **initial submission or revision** of an MOU?

A: MOUs for new reliance arrangements for IRBs that must be designated on the FWA must be submitted for review and approval by ORD and ORO prior to signature. Drafts of changes to existing (already approved) MOUs are not required to be reviewed by ORO prior to finalization. VISN Directors are not required to sign MOUs. MOUs (new or revised) for IRBs required to be designated on the FWA must be submitted to ORO within 30 days of execution. *See* VHA Directive 1058.03 §7.d(2).

Q: What is required in an MOU?

A: An MOU must include details that document roles and responsibilities of each institution regarding the use of another entity's IRB as a facility's IRB of Record. See ORO's MOU Checklist at http://www.va.gov/ORO/orochecklists.asp for information that should be included in an MOU. Some MOUs are developed by VA Central Office for national use.

Q: When do MOUs need to be reviewed/revised by the facility?

A: Existing MOUs must be revised promptly by the VA medical facility Director as conditions outlined in the MOU change and must be submitted to ORO (for IRBs that must be designated on the FWA) within 30 days of being revised as final.

Q: Who is responsible for maintaining MOUs?

A: The responsibility for maintaining the currency and accuracy of the MOU is a facility responsibility. ORO recommends facility staff be assigned to maintain the MOUs. MOUs will continue to be reviewed by ORO for compliance in the course of ORO compliance activities such as Combined Program Reviews.

Additional information for VA nonprofits

Q: Do VA nonprofits follow VHA Directive 1058.03?

A: No. VA nonprofits follow HHS-OHRP requirements, ORD requirements of VHA Handbook 1200.17, and relevant ORD guidance. *See* VHA Directive 1058.03 §2.c.

Q: Does our Non-Profit Corporation (NPC) need to complete the VA FWA Addendum?

A: No.

Q: Who can sign the NPC FWA?

A: The person who signs the FWA should be the person serving as the NPC Signatory/Institutional Official for the purposes of signing the Cooperative Research and Development Agreements and other MOUs or agreements such as the Executive Director or CEO. If the NPC Signatory Official is a medical facility Director or other Statutory Board member, their NPC titles must be used rather than their VA position titles.

Q: When does our NPC need to have an FWA?

A: For purposes of the requirement to maintain an FWA under the Common Rule, NPCs are deemed to be engaged in human subjects research when they are the direct recipients of or are administering the funds for the VA Institution through a grant, contract, or cooperative agreement from HHS or any of the federal agencies or departments applying the Common Rule. NPCs must follow the HHS-OHRP requirements, ORD requirements in VHA Handbook 1200.17, and any relevant ORD guidance.

Q: What IRBs must be designated on the NPC FWA?

A: Unless the VA NPC has a specific internal SOP requiring all IRBs it uses to be listed on its FWA, the VA NPCs would only be required to designate the VA IRB that they rely upon, or, if they do not rely upon a VA IRB, the academic affiliate IRB reviewing the greatest percentage of the VA research. There is no requirement to add additional IRBs such as the commercial IRBs (external IRB) to their FWAs because it is unlikely that the commercial IRBs will be reviewing the largest percentage of research to which their respective FWAs apply. Additionally, there is no requirement to remove IRBs already listed on the FWA if they are still being relied upon.